

U.S. Patent Application No. 10/681,352
Amendment dated August 20, 2007
Reply to Office Action of May 31, 2007

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REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

Claims 1-24 are canceled. Claims 25-26 have been amended. Claims 27-28 have been withdrawn. Support for the amendments to the claims can be found, for example, at pages 18-19 and 22-23 of the present application. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

Claim of Priority

At page 2 of the Office Action, the Examiner indicates that the benefit of priority has not been granted because certified copies of the two foreign applications filed in Japan have not been filed.

In response, the applicant respectfully points out that the two certified copies of the Japanese priority documents were filed on December 28, 2006. The applicant submits herewith a copy of the date-stamped postcard from the USPTO indicating receipt of these documents. Acknowledgement of the priority documents is therefore respectfully requested.

Objection to Claim 25

At the top of page 3 of the Office Action, the Examiner objects to claim 25. The Examiner states that claim 25 contains several acronyms, each of which should be appropriately identified with their full names.

To assist the Examiner, the applicant has amended claim 25 to include the appropriate full names for the acronyms listed in the claim. Accordingly, this objection should be

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withdrawn.

Rejection of Claims 25-26 Under 35 U.S.C. §112, Second Paragraph

At page 3 of the Office Action, the Examiner rejects claims 25-26 under 35 U.S.C. §112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner rejects the claims and asserts the following:

1) The Examiner states that the metes and bounds of claim 25 is not clear because the preamble of claim 25 recites "a method for determining treatments for a cancer patient" while the method steps, lines 2-12, are directed to methods which result in correlating encoded amino acid positions with a cancer treatment."

2) The Examiner states that the word "correlating" in claim 25 is vague and indefinite and that it is unclear as to how the method step of "correlating" encoded amino acids at particular positions with a cancer treatment is performed.

3) The Examiner states that the word "the positions" of claim 25 is vague and indefinite because the Examiner states that it is unclear to which positions of which gene are being referred as antecedent basis has been established with reference to three different groups of "positions" on three different genes.

4) The Examiner states that the wording "statically significant probability" used in claim 25 is vague and indefinite as it is unclear as to what the word "statically" refers.

5) The Examiner states there is insufficient antecedent basis for the wording "the greatest statically significant probability" in claim 25.

6) The Examiner states that the wording "the cancer patient comprises stomach cancer" in claim 25 is vague and indefinite.

These rejections are respectfully traversed.

Claims 25 and 26, have been amended to even more particularly point out the nature of the claimed invention. The claims clearly comply with §112, second paragraph. Accordingly, the applicant respectfully requests the Examiner to withdraw this rejection.

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Rejection of Claims 25-26 Under 35 U.S.C. §103(a) – Davies et al. in view of Lee et al. and further in view of Santamaria et al.

At page 5 of the Office Action, the Examiner states that claims 25-26 are rejected under 35 U.S.C. §103(a) as being obvious over Davies et al. (J. Clinical Oncology, vol. 19, pp. 1279-1287, 2001) in view of Lee et al. (Gastroenterology, vol. 111, pp. 426-432, 1996) and further in view of Santamaria et al. (U.S. Patent No. 5,972,604). This rejection is respectfully traversed.

Davies et al. does not teach or suggest a method for determining treatments for a cancer patient, which involves determining what amino acids are encoded by the recited positions of the HLA DQB1* gene of the patient, determining what amino acids are encoded by the recited positions of the DRB1* gene of the patient, and determining what amino acids are encoded by the recited positions of the DPB1* gene of the patient. Davies et al. also fails to disclose the step of determining a cancer treatment having a statistically significant probability of prolonging the patient's survival based on the amino acids encoded at the recited positions, wherein the cancer treatment is immunotherapy, chemotherapy, resection, or a combination thereof, as recited in the claims. In particular, the applicant notes that the studies conducted in Davies et al. involved intensively timed chemotherapy treatments provided to children with acute myeloid leukemia (AML) only. Davies et al. acknowledges that "future studies" must be conducted to determine "the broader applicability" of the published findings to other chemotherapy regimens (p. 1284, last paragraph). Davies et al. also makes no mention of treatments involving immunotherapy or resection.

Additionally, the applicant submits that Lee et al. and Santamaria et al. do not alone, or in combination, overcome the deficiencies identified in Davies et al. The Examiner refers to the disclosure in Lee et al. which states that HLA-DQB1 *0310 is more common in patients with

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gastric adenocarcinoma than non-cancer controls. However, the Examiner does not indicate how one could determine the optimal treatment for such patients, even if one were to rely on the disclosure in Davies et al., since Davies et al. only discusses the results of intensively timed chemotherapy treatments provided to children with acute myeloid leukemia (AML). Therefore, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,



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Attachment: Copy of USPTO date-stamped postcard dated December 28, 2006 (1 pg.)